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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,665	12/17/2001	Michelle R. Arkin	36632-0007	2694

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CAROLYN A. FAVORITO
MORRISON & FOERSTER LLP
3811 VALLEY CENTER DRIVE
SUITE 500
SAN DIEGO, CA 92130-2332

EXAMINER

RAO, DEEPAK R

ART UNIT PAPER NUMBER

1624

DATE MAILED: 11/14/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/024,665

Applicant(s)

Arkin et al.

Examiner

Deepak Rao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 8, 2003
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-40 ☒ are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-40 ☒ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 12 6) ☐ Other:

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DETAILED ACTION

This office action is in response to the amendment filed on August 8, 2003.

Claims 21-40 are pending in this application.

The following rejections are withdrawn:

The objections and rejections of the previous office action are rendered moot by the cancellation of the claims.

The following rejections are necessitated by the amendment:

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 21, the definition of J has been amended by the addition of the group “-NH-(C₂-C₆alkyl)-”, which group was not described in the originally filed specification. Applicant submits that the support for this group is in original claim 10, however, claim 10 only provides

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that 'B-J together represent -C(=O)-NH-(C₂-C₆alkyl)-, -S(=O)₂-NH-(C₂-C₆alkyl)-'. The instant recitation on the other hand leads to many other combinations of 'B-J', e.g., -CH₂-CH₂-NH-(C₂-C₆alkyl)-, -CH₂-O-CH₂-NH-(C₂-C₆alkyl)-, etc., which are not described for the claimed genus in the specification as filed. The recitation in claim 10 is not sufficient to support the addition of the group "-NH-(C₂-C₆alkyl)-" for J because such group was not originally described for the entire genus.

Applicant further relies on groups -C(=O)-NH-CH₂- or -S(=O)₂-NH- under the definition of B and the group -CHR¹⁵- under the definition of J to provide for the B-J combinations {i.e., -C(=O)-NH-(C₂-C₆alkyl)- and -S(=O)₂-NH-(C₂-C₆alkyl)- that were rejected as lacking antecedent basis in the previous office action}. First, in the original disclosure and/or claims, J is not defined to represent the single moiety -CHR¹⁵-. Further, R¹⁵ in this group is a monovalent moiety and therefore, the above group only covers for -CH(C₁-C₁₂alkyl)-, i.e., -CH(methyl)-, -CH(ethyl)- etc. whereas the inserted definition of -NH-(C₂-C₆alkyl)- includes many other groups such as -NH-(CH₂)₃-, -NH-(CH₂)₄-, etc. for which there is no support in the original disclosure.

Also, in claims 21 and 30, the definition of R⁹ is amended by the addition of the groups "=NH and -CH=NH" for which there is no support in the application as filed. Applicant relies on the disclosure in page 10, lines 4-11 as support for the above amendment, however, the disclosure on page 10 provides =NH and -CH=NH as substituents on a few of the disclosed heterocyclic moieties disclosed. The above insertion of the groups =NH and -CH=NH for R⁹ is not described for the entire claimed genus and therefore, the amended definition of R⁹ results in

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myriad of species which were not made or contemplated. Further, the modification of the definition of R^9 as it appears in the newly presented claims also changes the scope of the term M because M is also defined as R^9 . There is no support for in the application as filed for M to represent =NH or -CH=NH.

Therefore, as discussed above, the instant amendment introduces subject matter that was not described in such a way as to reasonably convey to one skilled in the art at the time the application was filed. The written description of a subgenus or species would not support claims to the generic element. "Disclosure of Two species in prior application did not provide written description to generic claims added in CIP", see *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 47 USPQ2d 1829 (Fed. Cir. 1998).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1. In claim 30, a definition for R^9 is provided, however, the structural formula II or the other variables do not contain such group. Therefore, the definitions of the terms R^9 - R^{14} in claim 30 are redundant. Further, on page 16, line 1, it is recited that " R^{14} together with

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the nitrogen to which it is attached...”, however, R¹⁴ is not disclosed to be attached to a nitrogen as can be seen from the definitions under R⁹.

2. In claim 31, formula III' does not appear within the claim and instead it is depicted immediately following claim 30, before the subheading of 'Claim 31 (New)'.

Appropriate amendment is suggested.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

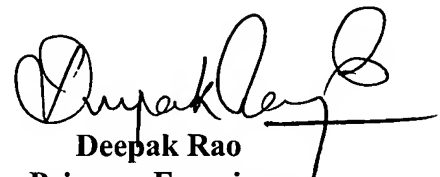
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (703) 305-1879. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (703) 308-4716. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Deepak Rao
Primary Examiner
Art Unit 1624

November 13, 2003